

### REMARKS/ARGUMENTS

Claims 1 - 38, 45 - 48 are pending. No claims have been amended.

- I. *Claims 1-5, 7-34, 36-38, and 45-48<sup>1</sup> are rejected under 35 USC 112, first paragraph, for not being enabling for other than the treatment of breast cancer with CCI-779 and an aromatase inhibitor (claim 6) and the treatment of an estrogen receptor positive carcinoma of the breast or ovary (claim 35) with CCI-779 and an aromatase inhibitor.*

Applicants respectfully traverse this rejection. MPEP §2164.01 summarizes the test for enablement as being whether one of skill in the art "can make and use the invention without undue experimentation."

Of the specific factors recited in In re Wands<sup>2</sup> for consideration in determining whether undue experimentation is required, the relative skill of those in the art is mentioned by the Examiner only in regard to the Board's decision in Ex parte Forman<sup>3</sup>. Unlike Ex parte Forman, where guidance was not provided as to how to obtain any of the claimed living attenuated oral vaccines, the present specification demonstrates a method of treating a neoplasm with a combination of CCI-779 and an aromatase inhibitor. The present specification also provides guidance as to a broad array of neoplasms for which the claimed methods, combinations, and compositions are useful.

The Examiner has also relied upon Pelosi<sup>4</sup> as support for the proposition that "[t]he pertinent art still deems neoplastic conditions/solid tumors as unpredictable in their clinical behavior." Applicants note that Pelosi is limited to discussion of a rare tumor type (seven total cases)<sup>5</sup>, rather than neoplasms generally.

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<sup>1</sup> Claims 39-44 were canceled in Applicants' Response filed November 9, 2007.

<sup>2</sup> 8 USPQ2d 1400 at 1404 (CAFC 1988).

<sup>3</sup> 230 USPQ 546 (BPAI 1986).

<sup>4</sup> Giuseppe Pelosi M.D., *et al.*, Mod. Pathol. 2001:14(5):521-526.

<sup>5</sup> *Id.* at Abstract.

In view of the guidance within the specification as a whole, one of skill in the art in treating neoplasms (a high level of skill) would be able to practice the full scope of the claims without undue experimentation. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection. In addition, Applicants note that given claim 35 is not rejected under this paragraph, claim 36 (which depends therefrom) should also not be rejected under this paragraph.

II. *Claims 1-41 and 45 – 48 have been rejected under 35 USC 102(e) as being anticipated by Dukart et al, US Published Patent Application 2003/0008923 A1 (Dukart).*

Applicants respectfully traverse this rejection.

The cited application requires a combination of an antineoplastic alkylating agent with the mTOR inhibitor. It is only in addition to that combination that a further component may be added. In the claimed invention of this application, no antineoplastic alkylating agent is required.

Reconsideration and withdrawal of this rejection is requested.


III. *Claims 42-44 are rejected under 35 USC 103(a), as allegedly unpatentable over Dukart in view of International Publication No. WO 2001/074335 ("Bertelsen").*

Applicants note that claims 39-44 were canceled in Applicants' Response filed November 9, 2007. Accordingly, this rejection is moot. Reconsideration and withdrawal of this rejection is requested.

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The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application to Deposit Account Number 08-3040.

Respectfully submitted,  
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